K092044

DEC 18 2009

510(k) Summary

SUBMITTED BY:	ORTHOCOR MEDICAL, Inc. 1000 Westgate Drive, Suite 243, Minneapolis, MN 55114 Registration: Awaiting Assignment
DATE PREPARED:	June 22, 2009
CONTACT:	Advanced Medical Consortium 9907 Oakleaf Way McCordsville, IN 46055 Tel: 651-641-2829
TRADE NAME:	OrthoCor Active Knee System
COMMON NAME:	Shortwave Diathermy
CLASSIFICATION NAME:	Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat Hot or cold disposable pack
DEVICE CLASS:	Class III
PRODUCT CODE:	ILX, 21 CFR 890.5290(b) IMD, 21 CFR 890.5710
PREDICATE:	Ivivi K070541 (Torino II) OrthoCor K091640

DEVICE DESCRIPTION

The OrthoCor Active Knee System is a portable (battery operated) non-invasive shortwave diathermy medical device which applies electromagnetic energy at a radio frequency (RF) of 27.12 MHz for the treatment of medical conditions by means other than the generation of deep heat within body tissues, i.e., by athermal means. The OrthoCor Knee System delivers the pulsed RF signal of $6.5 \pm 0.5 \mu Ws/cm^3$ to the tissue target via the inductive coupling with an applicator coil. The system also includes disposable, single-use, air activated OrthoPods that provide heat. The OrthoPods are snapped into medial and lateral slots on the knee wrap. Treatment may occur directly through dressings, clothing, casts, compression garments or supports. The OrthoCor device is substantial equivalent to the Ivivi Torino II device in parameters, treatment and power

INTENDED USE

- Adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue.
- Temporary relief of minor muscular and joint aches and pains associated with overexertion, strains, sprains, and arthritis

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Equivalence was based on bench testing that showed the device produces the same outputs as the predicate as shown in the table below.

COMPARISON TO PREDICATE DEVICES(s)

The OrthoCor Medical, OrthoCor Active Knee System has the same intended use, target population, clinical setting, and technology as its predicate devices.

Device Features	Predicate IVIVI Torino II K070541	OrthoCor Active Knee System
Technology	Deposit athermal RF energy in tissue	Deposit athermal RF energy in tissue
Anatomical sites	Superficial soft tissues	Superficial soft tissues (knee)
Practitioner	Licensed physician/chiropractor	Licensed physician/chiropractor
Portable	Yes	Yes
How Energy Deposited	Induction (coil applicator)	Induction
Carrier Frequency	27.12 MHz	27.12 MHz ± 5%
Burst duration	2msec	2msec
Burst frequency--	2Hz	2Hz
Energy Deposited Per Pulse	6.5 μWs/cm^3	6.5 μWs/cm^3
Electrical safety	Conforms with IEC 60601-1	Conforms with IEC 60601-1
Electromagnetic safety	Conforms with IEC 60601-1-2	Conforms with IEC 60601-1-2
Power required	Battery or Mains	3V-4.2V DC (battery)

STANDARDS MET

- IEC 60601-1 *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2 *Medical Electrical Equipment- Part 2: General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests*

CONCLUSION

OrthoCor Medical, Inc. believes that the OrthoCor Active Knee System Basic is substantially equivalent to the predicate device based on intended usage, technology comparison and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 18 2009

OrthoCor Medical, Inc.
% Advanced Medical Consortium
Ms. Ines Burgos
9907 Oakleaf Way
McCordsville, IN 46055

Re: K092044
Trade/Device Name: OrthoCor Knee System
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Regulatory Class: Class III
Product Code: ILX, IMD
Dated: November 27, 2009
Received: December 3, 2009

Dear Ms. Burgos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number:

Device Name: OrthoCor Knee System

Indications for Use:

OrthoCor Knee System is indicated for adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue.

Temporary relief of minor muscular and joint aches and pains associated with over-exertion, strains, sprains, and arthritis.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092044